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SECTION 5 – 510(k) Summary

APR 1 3 2009

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Contact:	Nancy Gertlar Director of Regulatory Affairs and Quality Assurance
Date Summary Prepared:	November 10, 2008
Trade Name:	Lifebed Network Patient Vigilance System
Common/Classification Name:	Monitor, Cardiac 74DRT, 870.2300
Substantially Equivalent Devices:	LG1 Patient Vigilance System (K052446); LifeBed Patient Vigilance System (K082366) Verathon Corp. BVI 9400 with ScanPoint (K071217) Diagnostic Ultrasound BVM6500 with ScanPoint (K030763)

Description of the LifeBed Network Patient Vigilance System:

The LifeBed Network Patient Vigilance System is identical to the LifeBed Patient Vigilance System described in the LifeBed Patient Vigilance System, K082366 with three exceptions.

A Controller as been added which will not be in the patient vicinity,
A wireless adapter has been added, and the
Indications for Use have been reworded.

The LifeBed Network integrates with the LifeBed Display to collect, store and report patient medical and status information.

The Display can be configured from the Network or from the Display. The Network and Display are connected using TCP/IP protocols. To ease logistical considerations at the

installation site, these two components are usually bridged across a wireless network using a LifeBed Wireless Adapter.

The Network also provides an interface which may be used to integrate with a clinical information system (CIS). When used in this way, an adapter box isolates and translates protocols between the Network and the CIS.

The Network centralizes information access and configuration for a group of Displays. It DOES NOT change the manner in which alerts are sent through the Nurse Call system of the hospital.

Each Display is a bedside unit that collects and processes data from a sensor array on the patients' bed. It reports patient heart rate, respiration rate, alarm and if the patient is in bed or out of bed to the Controller. This information is NOT displayed real time and is NOT to be used as a method to monitor the patient.

The hub of the Network is the LifeBed Controller which serves one unit (e.g., a hospital ward). From the Controller the user has full access to the information gathered from the unit and configuration of all of the Displays in the unit. The Controller also provides the interface used to integrate into a CIS or with a future product.

All user access to the Network is constrained by a security system. There are two factors involved: the individual user's role and the specific access permissions assigned to the user. The user's role constrains the type of data the user has access to (e.g. medical, device status, etc.). By default, all users have specific access to information sourced by their organization. Permission to access data sourced by another organization is denied unless specifically allowed.

The Network operates in a medical setting and must comply with relevant regulatory agency and legal requirements. As a medical product the Network must protect patient privacy. It must comply with all the requirements of the HIPAA Act.

Indication for Use

LifeBed Network Patient Vigilance System is intended to measure heart rate, respiratory rate, and bed exit in adult patients for use by health care professionals.

LifeBed Patient Vigilance System is intended to measure heart rate and respiratory rate in adult patients, in bed, in a general care hospital environment. The system will also monitor bed exit. K082366

Principles of Operation

The LifeBed Network is an extension of the LifeBed Display that collects, stores and reports patient medical and device status information. It is not intended to replace nurse call or other reports systems. It does not alarm. The LifeBed Network does not provide real time data for the purposes of diagnosing or treatment.

The LifeBed Network extends the LifeBed Display to collect, store and report patient medical and status information. The Network and Display are connected using TCP/IP protocols. To ease logistical considerations at the installation site, these two components (The Network and the Display) are usually bridged across a wireless network using a LifeBed Wireless Adapter.

The Network centralizes information access for a group of Displays. Each Display is a bedside unit that collects and processes data from a sensor array on the patient's bed. It reports patient heart rate, respiratory rate, alarm, and status information to the Controller.

The hub of the Network is the LifeBed Controller which serves one unit (e.g. a hospital ward. From the Controller the user has full access to the information gathered from the unit and configuration of all the Displays in its unit. The Network also allows for reports to be configured and sent by email, using an email to SMS gateway to mobile phones. These reports are NOT alarms and are not real time. Just as when reading from the Controller, the data in the reports is historical in perspective, only.

Users access information via the user interface, which runs on the Controller. All user access to the Network is constrained by a security system. Each user is assigned a role which constrains what type of data the user can access.

The Network operates in a medical setting and complies with the relevant regulatory agency and legal requirements. Wireless components are used to connect Displays to the Controller. The Controller will not be in the patient vicinity. As a medical product the Network must protect patient privacy. It must comply with all the requirements of the HIPAA Act.

All components of the Network interface via TCP/IP over Ethernet. There may be intermediate hardware to transport TCP/IP. Commonly, this will be a wireless network and the LifeBed Wireless Adapter will accommodate the configuration.

There are two software interfaces in the Network, the connection to the Display. The user interface and the proprietary protocol, Beacon.

Electrical, Mechanical and EMC Testing for the LifeBed Network Patient Vigilance System, patient vicinity components:

Test reports are found in section 17.

Electrical, Mechanical and EMC Testing for the LifeBed Network Patient Vigilance System, non-patient vicinity components:

- The LifeBed Network Controller is located in the IT department equipment areas within the hospital and classified as non-patient vicinity or contacting equipment. This equipment falls within the Information Technology Equipment category and is tested to the appropriate standards for safety and EMI compliance.
- The Wireless Adapter is attached to the LifeBed Display in the patient room and, therefore, is test to the appropriate standards for patient monitoring equipment.

Test reports are found in section 17.

Biocompatibility Testing

No changes were made to the Coverlet, which is the patient contacting surface. No biocompatibility tests were conducted as part of this submission.

Clinical Testing

No changes were made to the LifeBed Patient Vigilance System which contains the algorithm and controls the patient interface (K082366). The LifeBed Network Patient Vigilance System only adds the networking capabilities. Therefore, no clinical trial tests were required to support this submission.

Conclusion

All verification and validation testing conducted demonstrate that the LifeBed Network Patient Vigilance System is substantially equivalent to the LifeBed Patient Vigilance System, K082366.

It has been further demonstrated that the wireless addition to the LifeBed Patient Vigilance System is substantially equivalent to the wireless Verathon BVI 9400, Diagnostic Ultrasound BVM 6500, and ScanPoint which transmits data, wirelessly, to an office or facility for later viewing, diagnosing, calibrating or archiving, K071217.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2009

Hoana Medical, Inc.
c//o Ms. Nancy Gertlar
Director, Regulatory Affairs and Quality Assurance
828 Fort Street Mall, Suite 620
Honolulu, HI 96813

Re: K083534
Trade/Device Name: LifeBed Network Patient Vigilance System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II (two)
Product Code: DRT
Dated: April 1, 2009
Received: April 3, 2009

Dear Ms. Gertlar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083534

Device Name: **LIFEBED NETWORK PATIENT VIGILANCE SYSTEM**

Indications for Use:

The LifeBed Network Patient Vigilance System is intended to measure heart rate, respiratory rate, and bed exit in adult patients for use by health care professionals.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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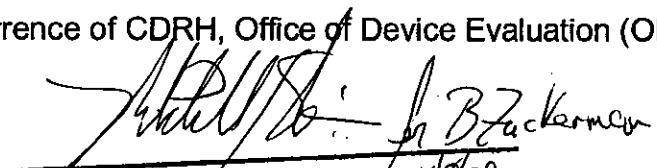
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off) 4/8/09
Division of Cardiovascular Devices

510(k) Number K083534